

REMARKS

Claim 4 is noted as being allowed.

A. Claims Rejected on Cigaina

The rejection of all but claim 16 (discussed below) and allowed claim 4 requires the application of Cigaina as prior art to the claimed structure of placing a band both above and below the cardiac notch:

- Claims 1, 3, 5 – 7, 13, 15 and 17 – 19 were rejected under 35 U.S.C. § 102(b) as anticipated by Cigaina WO 01/41671 A2 (Cigaina).
- Claims 2 and 14 were deemed obvious in view of Cigaina without a secondary reference.
- Claims 8 – 13 and 20 – 23 were rejected as obvious in view of Cigaina in combination with U.S. patent application 2002/0193842 A1 (Forsell).

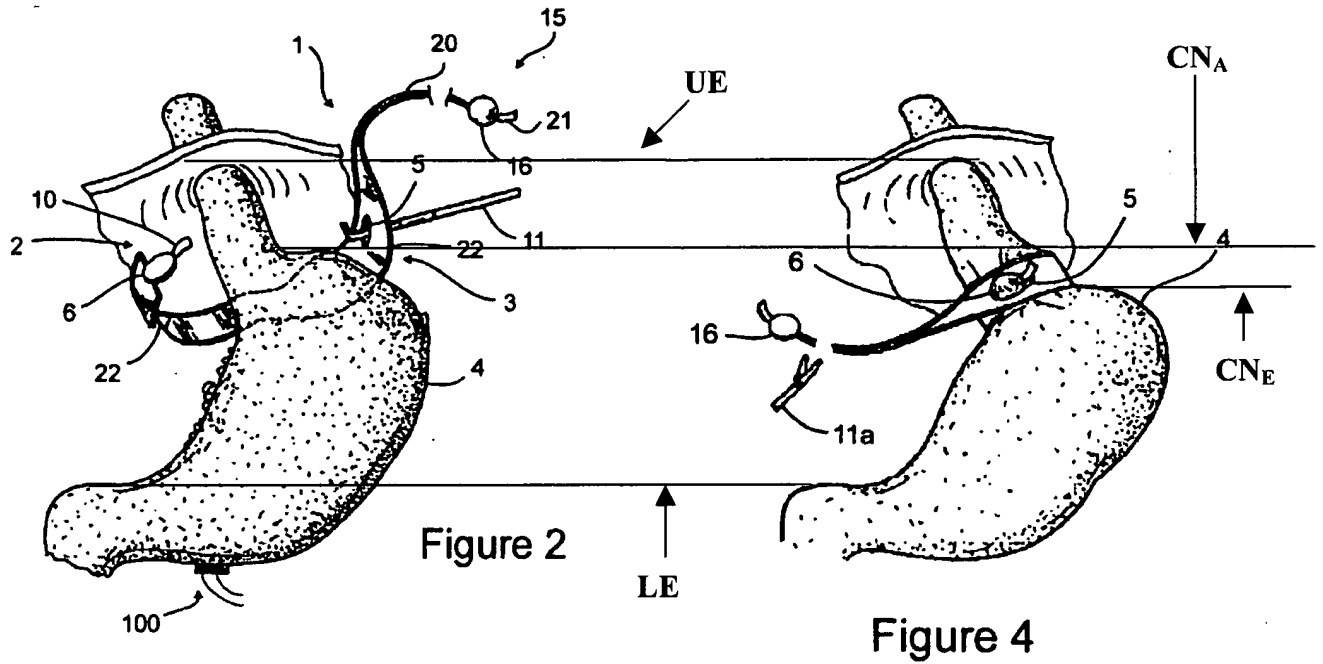
Therefore, the rejection of claims 1 – 3, 5 – 14 and 17 – 20 is premised upon the accuracy of the Examiner's opinion that Cigaina teaches placing a portion of the band both above and below the cardiac notch (the junction of the esophagus and the stomach). Applicant respectfully requests reconsideration of this conclusion.

a. The Drawings of Cigaina Indicate No Portion of the Band of Cigaina Is Placed Above the Cardiac Notch and on the Esophagus

The Examiner's hand drawings of the placement of the cardiac notch CN in Figs. 2 and 4 does not support anticipation. The drawings and hand-written notations are not to scale. Furthermore, they move the location of the cardiac notch CN between these two drawings. In fact, a detailed comparison of the drawings shows that no portion of the band of Cigaina resides above the cardiac notch and on the esophagus.

The side-by-side comparison, below, illustrates this error. In the following drawings copied from Cigaina (and reduced in size to fit on this page), upper and lower extremities (UE, LE) are shown such that, as reproduced herein, Figs. 2 and 4 are shown in proper scale relative to one another. The upper extremity UE is marked at the point the esophagus passes through the diaphragm. The lower extremity LE is the top of the duodenal bulb.

The actual position of the cardiac notch is shown by line CN_A. The position as drawn by the Examiner on Fig. 4 is shown as CN_E. In this representation, the actual cardiac notch CN_A remains above the band.



In the foregoing, Applicant has made a best effort using the word processing technology known to Applicant. Applicant is mindful that patent drawings are not required (and therefore not presumed) to be drawn to proper scale. Further, Applicant cannot represent that Cigaina intended Figs. 2 and 4 to be of comparable scale. As result, while the foregoing is not, by itself, proof that the band is not on the esophagus, it does establish that Figs. 2 and 4 do not clearly show the structure and method of Applicant's claims. M.P.E.P. § 2125.

However, Figs. 5A and 5B do clearly show that no part of the Cigaina structure overlies the esophagus. In these figures, the band is shown deflated (Fig. 5A) and inflated (Fig. 5B) over the stomach (element number 4) with no reference being made or shown to any structure overlying the esophagus.

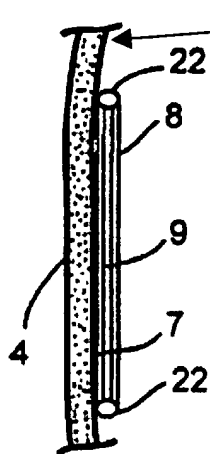


Figure 5A

Stomach 4 (not esophagus) is the only anatomy shown as being covered by Cigaina gastric band components.

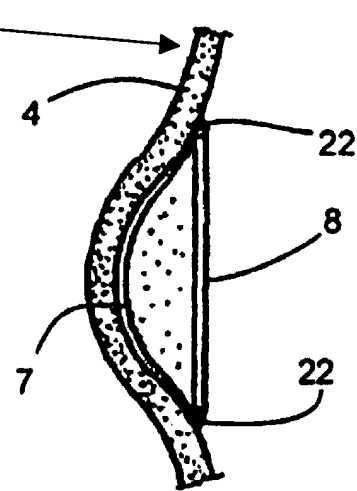


Figure 5B

B. The Text of Cigaina Indicate No Portion of the Band of Cigaina Is Placed Above the Cardiac Notch and on the Esophagus

The representative text passages of Cigaina are:

- P. 1, line 6 – 8: “The present invention relates to a removable gastric band which can be used to control obesity by allowing control ... of the diameter of a patient’s stomach.” (Emphasis added. Note, no mention of placement on esophagus).
- P. 2, lines 10 – 12: The invention is a “gastric band comprising an elongated body ... to close around a portion of the stomach.” (Emphasis added. Note, no mention of placement on esophagus).
- P. 2, line 19: The elongated body closes “around a section of the stomach.” (Emphasis added. Note, no mention of placement on esophagus).
- P. 2, lines 27 - 30: The gastric band is positioned and locked “around a section of the stomach.” (Emphasis added. Note, no mention of placement on esophagus).
- P. 3, line 1 – 2: The gastric band is adjusted “to control the stomach’s diameter in the section of the patient’s stomach.” (Emphasis added. Note, no mention of placement on esophagus).
- P. 4, lines 28 – 30: The gastric band surrounds “a portion, preferably the proximal tract, of the patient’s stomach.” (Emphasis added. Note, no mention of placement on esophagus).
- P. 5, lines 2 – 3: “Once locked into place, the gastric band 1 completely encircles and compresses a portion of the patient’s stomach.” (Emphasis added. Note, no mention of placement on esophagus).
- P. 6, lines 3 – 4: “Compression of the stomach using the gastric band of the present invention allows for a reduction of the stomach volume as desired.”

- P. 8, lines 13 – 14: “The elongated body is inflated until the desired degree of compression of the stomach occurs.” (Emphasis added. Note, no mention of placement on esophagus).
- P. 8, lines 28 – 30: “Using such a technique, the diameter of the gastric constriction provided by the gastric band can be modified or adjusted as desired.” (Emphasis added. Note, no mention of placement on esophagus).
- P. 9, line 32: The expandability of the device “is linked to the limit of compressibility of the gastric walls ...”. (Emphasis added. Note, no mention of placement on esophagus).

A careful review of the text of Cigaina reveals no reference to placement of any portion of the band on the esophagus. Clearly, Cigaina is limited to an improvement in old and well-known gastric bands to treat obesity. Such bands are disclosed in the present application on page 5 beginning at line 5. Cigaina only purports to describe a gastric band with enhanced removability.

In Cigaina (as in all such prior art gastric band), the band is not placed around the esophagus. Instead, the band is placed around the stomach (not the esophagus) to create a reduced diameter in the stomach (not the esophagus). This results in creation of a small stomach pouch above the band, which is connected to the bulk of the stomach beneath the band by a small, restricted passage formed by the band. As a result of making a reduced diameter stomach (not the esophagus), a patient can only consume a very small volume of food before feeling satiety.

Such prior art gastric banding procedures are not treatments for gastric reflux disease. The bands do not restrict or elongate the esophagus and do not reposition the cardiac notch (the junction point between the esophagus and the upper portion of the stomach). Instead, food which is consumed remains in the small pouch of the stomach above the band and can be regurgitated into the esophagus.

The present invention is not directed towards creating a small pouch of the stomach beneath the esophagus. Instead, the present invention provides a restriction along the entire length of the reducing element 10 to form a lengthening of the esophagus and a repositioning of the cardiac notch. It would not be obvious to modify Cigaina in either its structure or positioning to lengthen the esophagus of the patient since it would defeat the intended purpose of gastric bands, which is to form a small gastric pouch

between the esophagus and the placement of the gastric band. Furthermore, nothing in Forsell suggests a device, which lengthens the esophagus.

Rejection Based on Hodapp

Claim 16 was rejected based solely on U.S. Pat. No. 4,218,814 (Hodapp) which teaches a tubular sheath for a conduit such as copper tubing. (Col. 1, line 15). There is nothing in Hodapp to suggest a device "dimensioned so as to be" placed around an esophagus and stomach as now recited in claim. 16.

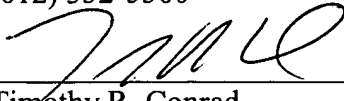
Applicant respectfully submits that reciting a device as so dimensioned is of patentable distinction over the prior art. Hodapp shows no such sizing. In Ex parte Crigler, 125 USPQ 448 (PTO Bd. of App. 1959), the Board, in a closely analogous case, held that claim language describing a size of a claimed element with reference to human anatomy was entitled to patentable weight. The Board reversed a final rejection and approved claim language stating "the adhesive on the surface is dimensioned so as to be attached by adhesion to continuous and spaced ear surfaces." 125 USPQ at p. 451 (emphasis added). The Board reasoned the quoted language "constitutes a structural limitation as to the size of the attaching means and therefore distinguishes from the [cited art]. Although the size of human ears varies, it is our opinion that neither [of the references] is dimensioned to fit on an ear and if either were made small enough to fit an ear, each would lose its usefulness for its disclosed purposes. 125 USPQ at p. 451 (emphasis added).

For the reasons given above, Applicants respectfully submit this application is now in condition for allowance. Reconsideration and Notice of Allowance are solicited.

Respectfully submitted,

MERCHANT & GOULD P.C.
P.O. Box 2903
Minneapolis, Minnesota 55402-0903
(612) 332-5300

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Timothy R. Conrad
Reg. No. 30,164
TRC:lmb